THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 11

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMES L. BERGEY, WERNER TSCHOLLAR, CARY S. YONCE and JAMES C. KAWANO

Appeal No. 94-2113
Application 07/801,207[1]

ON BRIEF

Before WINTERS and WILLIAM F. SMITH, Administrative Patent Judges, and McKELVEY, Senior Administrative Patent Judge.

Per Curiam

Decision on appeal under 35 U.S.C. § 134

The appeal is from a decision of the Primary Examiner rejecting claims 1 to 4, 11 to 16 and 19-28. The examiner and applicants seem to agree on the essential facts. We affirm but

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[1] Application for patent filed December 2, 1991, which is a continuation-in-part of Application Number 07/524,266 filed May 15, 1990. The real party in interest is Bristol-Myers Squibb Company.

designate our affirmance as a new ground of rejection under 37 C.F.R. § 1.196(b).

Applicants do not address the separate patentability of any particular claim (Appeal Brief, page 2). Hence, the claims stand or fall together with independent process claim 1.

Independent process claim 1 reads:

> A method for stabilizing or causing regression of atherosclerosis in a mammalian specie (sic--species), which comprises administering to a mammalian specie (sic--species) in need of such treatment an effective amount of a combination of a cholesterol lowering drug and an angiotensin converting enzyme inhibitor.

All other claims depend directly or indirectly from claim 1.

An example of a cholesterol lowering drug is said to be pravastatin (specification, page 1, line 17). An example of an angiotensin converting enzyme (ACE) inhibitor is said to be captopril (specification, page 1, line 19).

The examiner has rejected claims 1 to 4, 11 to 16 and 19 to 28 as being unpatentable under 35 U.S.C. § 103 over the prior art, in particular the combination of Cecil, Costa et al., Weinstein et al., Someya et al. and Hoffman et al. The examiner

has additionally rejected claims 1 to 4, 11 to 16 and 19 to 28 as being unpatentable under 35 U.S.C. § 103 over the prior art, in particular the combination Hoffman et al. and Aberg et al.

The examiner found, and applicants do not seem to disagree, that Cecil discloses that high cholesterol levels and hypertension are major risks factors for atherosclerosis. (Appeal Brief, page 5; Examiner's Answer, page 4).

The examiner found, and applicants do not seem to disagree, that Costa et al., Weinstein et al. and Someya et al. describe that hypertension accelerates the progress of atherosclerosis and that atherosclerotic mammals treated with ACE inhibitors showed a regression in their atherosclerotic symptoms. (Examiner's Answer, page 4).

The examiner found, and applicants do not seem to disagree, that Hoffman et al. describes the use of cholesterol lowering drugs to treat hypercholesterolemia, a known risk factor in atherosclerosis. (Examiner's Answer, page 4).

The examiner found, and applicants do not seem to disagree, that Aberg et al. describes ACE inhibitors *** to be useful in stabilizing or causing a regression of atherosclerosis. (Examiner's Answer, page 5).

The only salient argument that is advanced by the applicants against the rejections is that none of the references describe or suggest the use of a combination of a cholesterol lowering drug

and an ACE inhibitor to stabilize or cause regression of atherosclerosis. The examiner's rejection is bottomed on the general rule that it would have been prima facie obvious to a person having ordinary skill in the art to use a mixture of two prior art compounds for a particular purpose where each prior art compound is known individually to be useful for that same purpose. Applicable precedent supports the examiner's application of the general rule. See, inter alia, (1) In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is also used for that purpose), cited by the examiner (Examiner's Answer, page 5); (2) In re Dial, 326 F.2d 430, 432, 140 USPQ 244, 245 (CCPA 1964) (same); (3) In re Crockett, 279 F.2d 274, 276, 126 USPQ 186, 188 (CCPA 1960) (same); and (4) In re Pinten, 459 F.2d 1053, 1055, 173 USPQ 801, 803 (CCPA 1972) (same).

Given that both cholesterol lowering drugs, such as pravastatin, and ACE inhibitors, such as captopril, are individually known to treat symptoms of atherosclerosis (specification, pages 3-4 and 6), on this record it would have been obvious, consistent with binding precedent and the general rule set out above, for one having ordinary skill in the art to

have used a mixture of a cholesterol lowering drug and an ACE inhibitor to treat stabilize or cause regression of atherosclerosis.

As with all general rules, there are exceptions. One exception, among others, is where the mixture produces some unexpected result. Applicants maintain that the mentioned exception applies in this case because use of mixture of a cholesterol lowering drug and an ACE inhibitor is said to produce a "synergistic result" (Appeal Brief, page 8). The evidence upon which applicants base their "synergistic result" argument apparently is that on pages 41-46 of the specification (Appeal Brief, page 8).

The examiner's position with respect to the evidence is unclear. The examiner's finding that the combination of the same amounts should produce at least an additive effect of 100% reduction in the atherosclerotic symptoms (Examiner's Answer, page 6) is not necessarily supported by the evidence. We have reviewed the data on pages 41-46 of the specification. The evidence upon which applicant relies (which we observe is not in the form of a declaration), does not make out a case for application of the exception to the general rule noted above.

The claims include what might be characterized as both (1) obvious subject matter (combinations where synergism has not been

shown to exist) and (2) unobvious subject matter (a particular combination where synergism may exist). Compare In re Muchmore, 433 F.2d 824, 826, 167 USPQ 681, 683 (CCPA 1970) (claims which include obvious subject matter and non-obvious subject matter are not patentable under 35 U.S.C. § 103).

The "evidence" of alleged synergism is not commensurate in scope with the breadth of the claims. It is well established that a showing of unexpected results generally must be commensurate in scope with the breadth of the claim sought to be patented. See, inter alia, (1) In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (showing of unexpected results must be commensurate in scope with breadth of claim); (2) In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990) (same); and (3) In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (same). Applicants' claim 1 covers the use of numerous cholesterol lowering drugs. See the extensive list of compounds described in the specification at page 17, line 6 through page 27, line 25. Applicants' claim 1 also covers the use of ACE inhibitors. See page 27, line 26 through page 30, line 11. Only product claim 28 is limited to a combination of pravastatin and captopril. No ratio of pravastatin to captopril is recited in the claim. The

specification says that the pravastatin to captopril ratio will [not may] be employed in a weight ratio to each other within the range of from 0.001:1 to about 1000:1 and preferably from about 0.05:1 to about 100:1 (specification, page 16, lines 9-12). Yet the claim covers any ratio. Thus, no claim is commensurate with the scope of any showing made in the specification.

On this record, there is no basis upon which to find that all or even a large number of, the numerous possible combinations described in the specification and covered by claim 1 produce synergistic and unexpected results. Because, applicants have not made a showing commensurate in scope with the breadth of claim 1 or, for that matter, any other claim, the exception to the general rule does not apply.

The decision of the examiner rejecting claims 1 to 4, 11 to 16 and 19-28 under 35 U.S.C. § 103 over the prior art should be affirmed.

Our rationale supporting the rejection differs from the rationale advanced by the examiner since no clear reasoning was given as to why the evidence of alleged unexpected results was unpersuasive. Accordingly, we designate our affirmance as a new ground of rejection made under the provisions of 37 C.F.R. § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice,

62 Fed. Reg. 53,131, 53,197 (Oct. 21, 1997)). 37 C.F.R. § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 C.F.R. § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . . .

37 C.F.R. § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 C.F.R. § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under 37 C.F.R. § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 C.F.R. § 1.196(b)(1), in order to preserve the right to seek review under 37 C.F.R. §§ 1.141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before

the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the by the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

(37 C.F.R. § 1.196(b))

SHERMAN D. WINTERS, Administrative Patent Judge	
WILLIAM F. SMITH, Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
FRED E. McKELVEY, Senior Administrative Patent Judge	

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